The Increasing Importance of Legal Counsel and Compliance and Their Interaction with Healthcare Boards, *2nd Edition*

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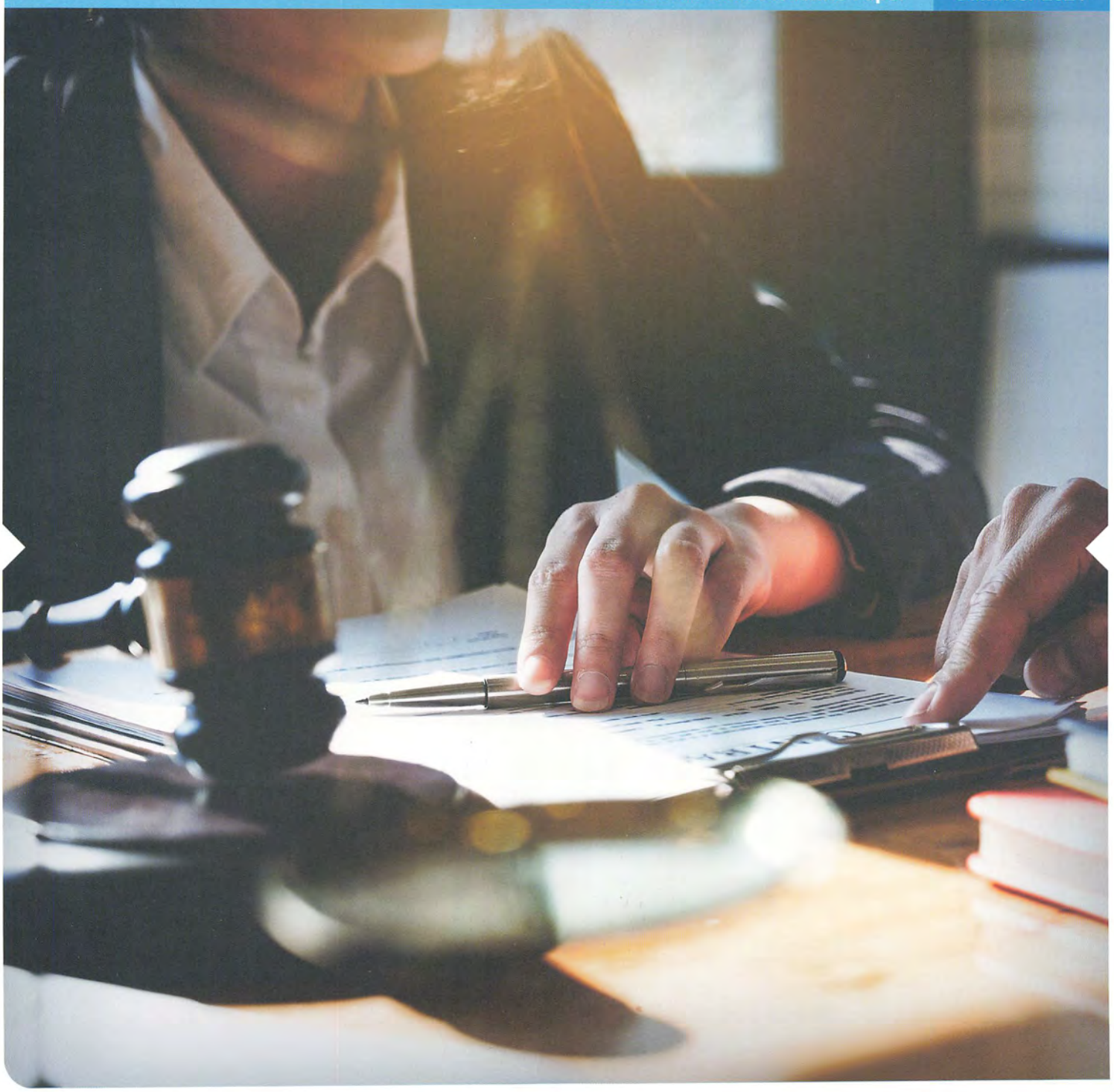

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Executive Summary

The roles of legal counsel and compliance officers in healthcare organizations are now more critical than ever. Scrutiny from government enforcement agencies continues to escalate, and financial recoveries from healthcare providers in the form of penalties and settlements are expected to increase.

Of the total $11.4 billion recovered over the last four years, $9 billion (approximately 80 percent) was recovered in healthcare fraud matters. This includes continuing emphasis on opioid addiction and treatment as the largest recoveries in the past year came from the drug industry.

Key Enforcement Areas of Focus

This white paper details the following key areas of current enforcement focus by the federal government:

- Physician compensation and the intersection of the False Claims Act, Stark Law, and Anti-Kickback Statute
- Private equity
- Data mining
- COVID-19 relief funds
- Speaking programs
- Rising number of whistleblower cases filed under the False Claims Act's *Quit tam* provisions
- The board's role in quality of care

It is vitally important for healthcare organizations to foster environments in which in-house and outside counsel are positioned to work effectively with the chief compliance officer and governing board.

The Differing Roles of Compliance and Legal Counsel

In light of the challenges described above and others, hospitals and health systems must increasingly rely on legal counsel to manage and mitigate risk associated with regulatory compliance. Additionally, it is vitally important for healthcare organizations to foster environments in which legal counsel—both in-house and outside counsel—are positioned to work effectively with the chief compliance officer and the governing board. It is critical for legal counsel and compliance officers to fully understand and appreciate their distinct roles within an organization:

- It is the compliance officer's role to operate and monitor the compliance program and investigate compliance issues.
- Legal counsel is charged with directing the organization's response to actual or potential violations.

However, the specifics of an organization's compliance program may depend largely on the size of the organization and the resources it has at its disposal. In situations where, due to the size of an organization or the available resources, a single individual is responsible for both the legal and compliance functions, it is of paramount importance that well-defined compliance policies and procedures are in place.

In addition to the importance of separating the compliance and legal functions, the board should receive regular reports regarding the organization's risk mitigation and compliance efforts in a format that satisfies the interests or concerns of its members and matches their ability to understand the information being presented.

The Seven Fundamental Elements of an Effective Compliance Program

In 2010, the U.S. Sentencing Commission released the Federal Sentencing Guidelines for organizations, including the provisions that set forth the attributes of effective compliance and ethics programs. Under the Federal Sentencing Guidelines, a convicted organization may be eligible for a reduced sentence if it has established an effective compliance and ethics program. The Guidelines (since updated in 2018) describe the key attributes that a compliance and ethics program must exhibit for the organization to be eligible to receive benefits such as reduced fines, reduced sentence, or deferred prosecution. The fundamental elements are:

1. Implement written policies, procedures, and standards of conduct.
2. Designate a compliance officer and compliance committee.
3. Conduct effective training and education.

4. Develop effective lines of communication.
5. Conduct internal monitoring and auditing.
6. Enforce standards through well-publicized disciplinary guidelines.
7. Respond promptly to detected offenses and undertaking corrective action.

After implementation, an organization can take the following steps to help maintain an effective compliance program:

- Set benchmarks and measurable goals.
- Measure attainment of goals regularly.
- Investigate failure to meet goals.
- Report results to the board.
- Assess where the problems are and suggest solutions.
- Provide adequate funding.
- Ensure sufficient support throughout the entity, including upper management.

In addition, the board must remain informed about:

- Outcomes
- Notices of non-compliance
- Results of internal and external audits
- Open/closed corrective action plans
- Corrective action appropriately and timely implemented and tested for effectiveness (CMS Mandatory Compliance Programs)

Organizations that establish an effective compliance program using the seven fundamental elements described in this white paper will position themselves for success in all areas, from reducing the organization's risk for legal liability to increased transparency, more effective reporting to the board leading to a better-informed board and more effective decision making, and ultimately, creating an organizational culture that supports patient safety and quality of care.

Introduction

For hospitals and health systems, the roles of legal counsel and compliance officers are now more critical than ever. Scrutiny from government enforcement agencies continues to escalate, and financial recoveries from healthcare providers in the form of penalties and settlements are expected to increase. In fiscal year 2020, the Department of Justice (DOJ) obtained $1.8 billion in healthcare fraud settlements and judgments from healthcare-related False Claims Act cases.[1] That brings the total of recoveries in healthcare cases to approximately $27 billion since fiscal year 2010.[2]

> Recent settlements underscore both the federal government's continuing commitment to pursue healthcare fraud and abuse cases and the increasingly important roles played by compliance officers and legal counsel at hospitals and healthcare systems.

These settlements underscore both the federal government's continuing commitment to pursue healthcare fraud and abuse cases and the increasingly important roles played by compliance officers and legal counsel at hospitals and healthcare systems.

This white paper details updated information related to key areas of enforcement focus by the federal government and potential implications of such enforcement focus for hospitals, health systems, and their boards. It explains the differing roles of the compliance officer and legal counsel and outlines the essential ingredients of an effective compliance program. It includes best practices related to the relationship between the board, compliance officer, and legal counsel, as well as the board's role and responsibilities regarding its monitoring of the compliance program and ensuring its effective enforcement.

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1 United States Department of Justice (U.S. DOJ), "Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020" (press release), Office of Public Affairs, Department of Justice, January 14, 2021.

2 Winston & Strawn LLP, "DOJ False Claims Act Recoveries Top $3 Billion, Continuing the Trends of Aggressive Health Care Industry Enforcement and Government-Initiated Actions." February 18, 2020.

Key Areas of Enforcement Focus

In December 2020, Deputy Assistant Attorney General Michael D. Granston made the following remarks at the ABA Civil False Claims Act and *Qui tam* Enforcement Institute: [3] of the total $11.4 billion recovered over the last four years, $9 billion (approximately 80 percent) was recovered in healthcare fraud matters. This includes continuing emphasis on opioid addiction and treatment as the largest recoveries in the past year came from the drug industry.

Granston noted that the DOJ has modified the 2015 Civil Division memoranda drafted by then-Deputy Attorney General Sally Quillian Yates. This update includes a "specific cooperation policy applicable to False Claims Act cases." Under this policy, corporate defendants can earn cooperation credit—and a possible reduction in penalties and damages—by "voluntarily disclosing misconduct, cooperating with pending investigations, and taking remedial measures." The DOJ also instituted policies to avoid the imposition of duplicative fines and penalties on organizations seeking to settle charges brought by the DOJ. Additionally, the DOJ's Civil Division adopted guidelines for settling cases based on a defendant's ability to pay. While these are welcome developments for hospitals and health systems, this is no time for complacency.

Physician Compensation and the Intersection of the False Claims Act, Stark Law, and Anti-Kickback Statute

While the opioid crisis dominated the enforcement headlines, any discussion of where healthcare enforcement is headed must include the intersection of the federal False Claims Act, the federal Stark Law, and the Anti-Kickback Statute and their state law equivalents. One notable matter in Oklahoma resulted in a $72.3 million settlement to resolve federal and state False Claims Act allegations stemming from improper payments to referring physicians.[4] Key players in the matter included a hospital, a management company, and a physician group. The charges involved (i) free or below fair market value office space, employees, and supplies, (ii) compensation in excess of fair market value for the services provided by Southwest Orthopaedic Specialists, PLLC and certain of its physicians, (iii) equity buyback provisions and payments for certain physicians that exceeded fair market value, and (iv) preferential investment opportunities in connection with the provision of anesthesia services.[5]

A second recent case involved a hospital in West Virginia that paid $50 million to settle allegations concerning improper compensation to referring physicians.[6] According to the DOJ, the hospital "violated the False Claims Act by knowingly submitting claims...that resulted from violations of the Physician Self-Referral Law and the Anti-Kickback Statute."[7]

While these two cases are comparatively low-profile in light of the large settlements being paid by pharmaceutical companies for their roles in the opioid crisis, hospital management and board members should recognize how a seven- or eight-figure settlement (and the resulting negative publicity) could be the death knell for hospitals already facing tight margins and difficult choices.

> The DOJ is using increasingly sophisticated tools for data analysis, predictive analytics, trend evaluation, and modeling to examine Medicare claims for known fraud patterns, identify suspected fraud trends, and calculate ratios of allowed services as compared to national averages.

Private Equity

In June 2020, when Principal Deputy Assistant Attorney General Ethan P. Davis[8] spoke about the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform, he remarked that private equity firms "should be aware of laws and regulations designed to prevent fraud" when they invest in companies in highly regulated industries like healthcare or life sciences.[9] For example, the DOJ brought False Claims Act charges against a

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3 U.S. DOJ, "Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute," December 2, 2020.
4 U.S. DOJ, "Oklahoma City Hospital, Management Company, And Physician Group To Pay $72.3 Million To Settle Federal And State False Claims Act Allegations Arising From Improper Payments To Referring Physicians" (press release), July 8, 2020.
5 *Ibid.*
6 U.S. DOJ, "West Virginia Hospital Agrees To Pay $50 Million To Settle Allegations Concerning Improper Compensation To Referring Physicians" (press release), September 9, 2020.
7 *Ibid.*
8 U.S. DOJ, "Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform," June 26, 2020.
9 *Ibid.*

private equity owner for violations related to one of its portfolio companies, a compounding pharmacy.[10] These charges were resolved in 2019 with a $21.3 million settlement paid by the compounding pharmacy, two of its executives, and the private equity firm.[11]

Another instance involved the private equity owner of a medical device company that was charged with promoting the use of certain immunotherapy instruments for unapproved uses in pediatric patients; the allegations extended from 2006–2015.[12] The private equity owner, having purchased the company in 2012, agreed to pay $1.5 million to settle the False Claims Act allegations for that period, and the former owner during the 2006–2012 period paid $10 million.[13]

Data Mining

The DOJ can be expected to increase the use of data analysis to identify potential fraud cases.[14] The DOJ is using increasingly sophisticated tools for data analysis, predictive analytics, trend evaluation, and modeling to examine Medicare claims for known fraud patterns, identify suspected fraud trends, and calculate ratios of allowed services as compared to national averages.[15] In addition, data analysis is also being used increasingly by whistleblowers developing False Claims Act actions under the Act's *qui tam* provisions (discussed in more detail below).

Enforcement agencies expect an organization to know its data. It is important to have software capable of analyzing a large volume of electronic billing information remotely. Agencies have access to all of your data and are becoming more and more experienced at evaluation, so it is important for management to be familiar with this data and capable of readily accessing it.

While intuitive software is important to the accessing of data, it is critical to be wary of evolving payment systems. As these systems continue to evolve, they can sometimes still carry a fair amount of risk to an organization. While the CMS Innovation Center is supportive of various solutions to payment tracking, there are still regulatory issues that have yet to be addressed with the systems currently provided. Remain cautious of any risky or unwise arrangements by asking if the software being evaluated improves quality or maintains quality at a lower cost. If quality is not improved, it's likely not a valuable resource to the organization.

COVID-19 Relief Funds

It remains to be seen how the government will handle enforcement against businesses that received CARES Act and other federal relief funds. However, while enforcement related to pandemic assistance in 2020 and early 2021 have largely focused on small businesses that filed fraudulent applications for funds, these early actions may pave the way for DOJ enforcement action against larger companies.[16]

Enforcement actions spanning March 2020 to March 2021 have focused mainly on obvious cases of fraud, such as fraudulent applications for PPP loans. In a public release in March 2021, the DOJ reported that it had "publicly charged 474 defendants with criminal offenses based on fraud schemes connected to the COVID-19 pandemic. These cases involve attempts to obtain over $569 million from the U.S. government and unsuspecting individuals through fraud."[17]

Expect the government to apply the same enforcement theories to large organizations soon, and for the focus to shift to things like fraudulent billing.[18]

Speaking Programs

In November 2020, the Department of Health and Human Services (HHS) released a Special Fraud Alert from the OIG highlighting the fraud and abuse risks associated with speaker programs sponsored by healthcare companies.[19]

The OIG and DOJ have investigated fraud cases involving allegations that compensation offered and paid in connection with speaker programs violated the Anti-Kickback Statute, and the federal government has pursued civil and criminal cases against pharmaceutical and medical device companies and individual healthcare professionals (HCPs) involving these speaker programs. From 2017 to 2019, drug and device companies have

10 Private Equity International, "False Claims Act: A new risk to private equity investors," December 2, 2020.
11 U.S. DOJ, "Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations" (press release), September 18, 2019.
12 U.S. DOJ, "Former Owners of Therakos, Inc. Pay $11.5 Million to Resolve False Claims Act Allegations of Promotion of Drug-Device System for Unapproved Uses to Pediatric Patients" (press release), November 19, 2020.
13 *Ibid.*
14 U.S. DOJ, December 2, 2020.
15 Centers for Medicare & Medicaid Services (CMS), "The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud," March 19, 2015.
16 The National Law Review, "COVID-19 Enforcement Trends One Year Into the Pandemic," March 30, 2021.
17 U.S. DOJ, "Justice Department Takes Action Against COVID-19 Fraud," March 26, 2021.
18 The National Law Review, March 30, 2021.
19 Office of the Inspector General, "Special Fraud Alert: Speaker Programs," Department of Health and Human Services, November 16, 2020.

reported paying nearly $2 billion to HCPs for speaker-related services.[20]

While healthcare company-sponsored speaking events were created to educate listeners regarding the use or value of a company's medical devices or medications, OIG revealed that often, "HCPs receive generous compensation to speak at programs offered under circumstances that are not conducive to learning or to speak to audience members who have no legitimate reason to attend."[21] These cases "strongly suggest that one purpose of the remuneration to the HCP speaker and attendees is to induce or reward referrals."[22]

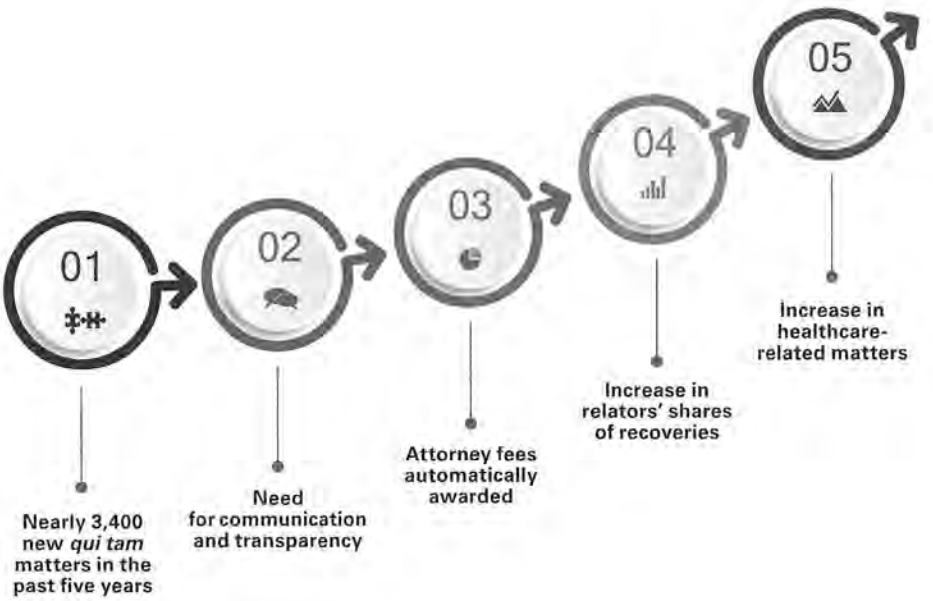
Below is a selection of the characteristics OIG listed in its Alert to provide an illustrative, though not exhaustive, list of features that indicate a speaker program arrangement could potentially violate the Anti-Kickback Statute:

- The company sponsors speaker programs where little or no substantive information is presented.
- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free).
- The program is held at a location that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues).
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information.
- There has been a significant period with no new medical or scientific information nor a new FDA-approved or cleared indication for the product.
- The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the HCPs.

Ultimately, OIG suggests that companies should assess the need for in-person programs, particularly given the risks associated with offering or paying related compensation and consider alternative, less-risky means for conveying information.

Rising Number of Whistleblower Cases Filed under the False Claims Act's *Qui tam* Provisions

Since the late 1980s, there has been a steady increase in the number of new fraud matters opened by the DOJ's Civil Division based on newly received referrals, investigations, and *qui tam* actions.[23] *Qui tam* actions involve a whistleblower, also known as a relator, who reveals misconduct by his or her employer or another business or entity. The majority of false claims actions are filed under the whistleblower, or *qui tam,* provisions of the False Claims Act. A whistleblower who exposes fraud can bring a *qui tam* lawsuit on behalf of the government and can receive a share of the recovery as his or her



20 CMS, "Open Payments Data Overview" (Web page, last modified May 3, 2021).
21 *Ibid.*
22 *Ibid.*
23 Civil Division, U.S. DOJ, Fraud Statistics Overview, October 1, 1986–September 30, 2020.

reward. In actions in which the government prevails, the whistleblower is eligible to receive up to 30 percent of the amount recovered in the form of fines, penalties, and/or settlements.[24]

In the past five years, the DOJ has opened nearly 3,400 new *qui tam* matters.[25] In total, newly opened matters have more than doubled from 371 in 1987 to nearly 922 in 2020.[26] Healthcare-related matters have increased over the same period from 15 in 1987 to 573 in 2020.[27] Even more dramatic is the shift of new matters based on *qui tam* actions. Until 1993, the majority of new healthcare-related matters opened each year were classified as non-*qui tam* matters by the DOJ.[28] Since 1993, however, the percentage of *qui tam* actions has skyrocketed. In 2020, 456 new healthcare matters were classified as *qui tam* actions compared to a mere 15 in 1992 non-*qui tam* matters.[29]

Additionally, attorneys' fees for the relator are automatically awarded. In 2020, relators filed 672 *qui tam* suits resulting in $2.2 billion in recoveries. The relators' shares of these recoveries came to nearly $310 million. In light of these potential monetary returns, the growth in *qui tam* actions is hardly surprising.

Equally troubling for hospitals and associated providers is the growing number of cases being pursued by relators despite the DOJ declining to intervene in the False Claims Act action. For many years after the 1986 amendment of the False Claims Act, the number of declined cases litigated by whistleblowers remains a looming threat.

The rapidly growing role of relators in initiating and pursuing False Claims Act cases—either with or without government involvement—means that hospitals must both:

- Be aware of the *qui tam* process.
- Take steps to reduce exposure to potential whistleblower actions.

The Role of the Relator in *Qui tam* Actions

A *qui tam* action may be filed by a private citizen whistleblower on behalf of the government. The relator must have inside information regarding a potential False Claims Act violation; allegations cannot be based on publicly disclosed information unless the relator was the source of the information. If the relator reports conduct that he or she reasonably believes constitutes illegal activity, the belief must be reasonable from a subjective and objective standpoint. The belief does not have to be *correct*, as long as it is *reasonable*.

Relators are often disgruntled or recently terminated employees, and they may even include auditing, legal or compliance personnel. Relators can also be third parties, such as a vendor responsible for handling compliance complaints. It's important to note that the relator can be the individual responsible for the false claims, for instance, an employee in the billing department who falsified records or a supervising physician who falsified sign-in logs showing she was present in the facility to supervise tests. Despite this seeming contradiction, the relator is still entitled to file a *qui tam* suit and share in the recovery, although the court has the discretion in these circumstances to reduce the relator's share.

> When employees see their concerns being addressed actively and responsibly, they are less likely to become whistleblowers. Conversely, employees who feel their complaints have fallen on deaf ears are more likely to pursue a *qui tam* action if they feel it is the only way to get management's attention.

Best Practices for Hospitals to Protect Against Whistleblower Lawsuits

In an increasingly aggressive environment for *qui tam* actions, there are many best practices that hospitals can follow to help protect against whistleblower lawsuits, such as:

1. Screen new hires carefully and incorporate adherence to the hospital's code of conduct into the expectations for every position.
2. The use of internal reporting procedures should be clearly defined and incorporated into employee evaluations. Supervisors and managers should be trained on how complaints and issues identified through those internal reporting procedures are to be addressed.
3. Supervisors and managers should respond promptly to troubled working relationships before employees become *disgruntled* and potential whistleblowers.
4. Employees should be reminded regularly of their duty to report illegal conduct, and annual performance

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24 U.S. DOJ, "Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015" (press release), Office of Public Affairs, December 3, 2015.
25 Civil Division, U.S. DOJ, Fraud Statistics Overview.
26 *Ibid.*
27 *Ibid.*
28 *Ibid.*
29 *Ibid.*

evaluations should include certification that each employee has disclosed any illegal activity of which he or she is aware.

5. Departing employees should confirm that they have disclosed any misconduct during their exit interviews.

If a current or departing employee has reported potentially illegal conduct, the disclosure should be taken seriously and investigated formally. When employees see their concerns being addressed actively and responsibly by management, they are often less likely to become whistleblowers. Conversely, employees who feel their complaints have fallen on deaf ears are more likely to pursue a *qui tam* action if they feel it is the only way to get management's attention. Hospitals should consider involving legal counsel in the investigations and remain mindful of attorney-client privilege issues.

In the event that an employee or other individual opts to pursue a *qui tam* action, the relator must file the case under seal and provide the government with a statement of material evidence. The government then has 60 days to investigate the relator's allegations and decide whether to intervene in the matter. This timeline, however, is frequently extended. During this period, the hospital may have no knowledge of a pending lawsuit, although the government's investigation may involve OIG subpoenas, Civil Investigative Demands, or even search warrants. The hospital's most important goal at this stage is to convince the government not to intervene in the matter. If the government decides to intervene, it will take over the case, though the relator could still participate. If the government declines, the relator may pursue the case as noted above, although at the relator's own expense. Any monetary recovery, however, will ultimately go to the government. Once the intervention decision is made, the case is unsealed and served on the defendant.

The Board's Role in Quality of Care

Payment policies that align payment with quality care have placed increasing pressure to conform to recommended quality guidelines and improve quality outcomes. In response to growing concerns about healthcare quality and patient safety, the government has launched numerous initiatives to increase quality and accountability in the healthcare system. In this new era, the government has charged boards of healthcare organizations with the overall responsibility for the quality of care delivered at their organizations. Boards are increasingly being held accountable for quality failures, which sometimes translates into legal liability.

One of the basic fiduciary duties is the duty of care, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances. This duty is being tested in the current climate. Embedded within the duty of care is the concept of reasonable inquiry, under which directors are expected to make inquiries to management to obtain the information necessary to satisfy their duty of care.

Board involvement is crucial to creating an organizational culture that supports patient safety and quality thus mitigating the potential application of the False Claims Act to quality of care issues. The board should be actively involved in designing a strategic imperative for the organization that focuses on healthcare quality and patient safety and regularly monitor progress toward goals. These comprehensive quality improvement programs will not only serve to avoid costly FCA litigation, but will improve the overall quality and patient safety in healthcare settings.

In 2011, the OIG created a "Tool Kit for Healthcare Boards" to use as a guideline for their responsibility as it relates to quality of care.[30] The OIG's recommendations include:

- Create a comprehensive policy and objectives to define your quality improvement and patient safety program.
- Ensure your stakeholders share a common vision of quality. To give your program real impact, incorporate its objectives into employee performance evaluations and incentive compensation.
- Establish a board quality committee and make quality of care a standing board agenda item.
- Ensure you have sufficient clinical expertise on the board. To address potential conflicts, some hospital boards recruit physicians who are not medical staff members, or who are retired.
- Understand how management assesses the credentials of the medical staff and stay current on best practices.
- Implement conflict-of-interest policies to identify and manage financial interests that may affect clinical judgment.
- Use dashboards and benchmarks to measure the success of your organization as it improves outcomes and patient satisfaction. You should track how your organization compares to its peers on these quality indicators. After all, "What gets measured is what gets done."

These areas of enforcement focus emphasize the continuing and increasing need for hospitals and health systems to have strong policies and programs in place, with the right leadership structure, to protect the organization and board from liability risk. The following sections of the white paper describe such structures and programs.

30 Health Care Fraud Prevention and Enforcement Action Team, "A Tool Kit for Health Care Boards," OIG, Department of Health and Human Services, 2011.

The Differing Roles of Compliance and Legal Counsel

In light of the challenges described above and others, hospitals and health systems must increasingly rely on legal counsel to manage and mitigate risk associated with regulatory compliance. Additionally, it is vitally important for healthcare organizations to foster environments in which legal counsel—both in-house and outside counsel—are positioned to work effectively with the chief compliance officer and the governing board. It is critical for legal counsel and compliance officers to fully understand and appreciate their distinct roles within an organization.[31] In April 2015, OIG issued "Guidance for Health Care Governing Boards on Compliance Oversight" in which the roles and relationships of the compliance and legal functions were concisely defined:[32]

- **Compliance:** "The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards."
- **Legal:** "The legal function advises the organization on the legal and regulatory risks of its business strategies, providing advice and counsel to management and the board about relevant laws and regulations that govern, relate to, or impact the organization."

It is the compliance officer's role to operate and monitor the compliance program and investigate compliance issues, while legal counsel is charged with "directing the organization's response to actual or potential violations."[33] Beyond the interpretation of the law, attorneys working with hospitals and health systems provide advice on ethical issues and how to promote a culture of compliance.[34] "Collaboration, not cohabitation," is viewed as the most effective relationship between compliance and in-house counsel, and while the two roles are related and complementary, it is optimal "to keep the roles separate and with an equal footing."[35] Nearly nine out of 10 respondents in a recent survey of compliance professionals voiced opposition to corporate counsel also serving as the compliance officer. The rejection of the idea "was particularly high among respondents from healthcare and the not-for-profit sector."[36] This is a long-held view by OIG, which noted in 1998 that "an organization's Compliance Officer should neither be counsel for the provider nor be subordinate in function or position to counsel or the legal department, in any manner."[37]

> Boards of smaller organizations may need to become more involved in the organizations' compliance and ethics efforts than their larger counterparts.

Despite its strong recommendations for separate compliance and legal functions, OIG recognizes that the specifics of an organization's compliance program may depend largely on the size of the organization and the resources it has at its disposal.[38] These organizations must, however, "demonstrate the same degree of commitment to ethical conduct and compliance as larger organizations."[39] While these programs may be less formal or may use available personnel instead of separate staff, OIG stresses that "boards of smaller organizations may need to become more involved in the organizations' compliance and ethics efforts than their larger counterparts."[40]

In situations where, due to the size of an organization or the available resources, a single individual is responsible for both the legal and compliance functions, it is of paramount importance that well-defined compliance policies and procedures are in place, "particularly with respect to the reporting of misconduct."[41] This will protect the compliance officer/legal counsel from the appearance of impropriety if an established protocol is followed precisely with step-by-step documentation of the procedures followed by the individual.[42]

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31 American Health Law Association (AHLA), "The Relationship between the Compliance Officer, In-house Counsel and Outside Counsel: An Essential Partnership for Managing and Mitigating Regulatory Risk," AHLA Fraud and Compliance Forum, October 2014.
32 Office of Inspector General (OIG), "Practical Guidance for Health Care Governing Boards on Compliance Oversight," U.S. Department of Health and Human Services, Association of Healthcare Internal Auditors, American Health Lawyers Association, Health Care Compliance Association, April 2015.
33 AHLA Fraud and Compliance Forum, October 2014.
34 "Managing the General Counsel/Compliance Officer Relationship," *AHLA Connections*, October 2011.
35 Society of Corporate Compliance and Ethics and the Health Care Compliance Association, "Should Compliance Report to the General Counsel?," March 2013.
36 *Ibid.*
37 OIG, April 2015.
38 *Ibid.*
39 *Ibid.*
40 *Ibid.*
41 AHLA Fraud and Compliance Forum, October 2014.
42 *Ibid.*

Provide Communication and Access to the Board

In addition to stressing the importance of separating the compliance and legal functions, OIG recommends that the board "should receive regular reports regarding the organization's risk mitigation and compliance efforts—separately and independently."[43] A 2018 survey of compliance and ethics professionals found that in the healthcare industry, two-thirds of compliance officers' reports to their respective boards were not pre-screened or edited by the general counsel or others.[44] Encouragingly, in the same survey, more than three-quarters of respondents reported that the chief compliance and ethics officer is responsible for escalating very serious allegations and/or investigations of non-compliance to the board, indicating that even where compliance reports to others, "in serious cases the board is contacted directly."[45]

For boards, ensuring open lines of communication throughout the organization is vital. OIG notes that a board can "raise its level of substantive expertise with respect to regulatory and compliance matters by adding to the board, or periodically consulting with, an experienced regulatory, compliance, or legal professional. The presence of a professional with healthcare compliance expertise on the board sends a strong message about the organization's commitment to compliance, provides a valuable resource to other Board members, and helps the board better fulfill its oversight obligations."[46] OIG also recommends that a board should receive compliance and risk-related information in a format that satisfies the interests or concerns of its members and matches their ability to understand the information being presented.[47]

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43 OIG, April 2015.

44 Society of Corporate Compliance and Ethics and the Health Care Compliance Association, "The Relationship between the Board of Directors and the Compliance and Ethics Officer," April 2018.

45 *Ibid.*

46 "Practical Guidance for Health Care Governing Boards on Compliance Oversight, Office of the Inspector General, U.S. Department of Health and Human Services, Association of Healthcare Internal Auditors, American Health Lawyers Association, Health Care Compliance Association, April 2015

47 *Ibid.*

The Seven Fundamental Elements of an Effective Compliance Program

In 2010, the U.S. Sentencing Commission released the Federal Sentencing Guidelines for organizations, including the provisions that set forth the attributes of effective compliance and ethics programs. Under the Federal Sentencing Guidelines, a convicted organization may be eligible for a reduced sentence if it has established an effective compliance and ethics program. The Guidelines (since updated in 2018) describe the key attributes that a compliance and ethics program must exhibit for the organization to be eligible to receive benefits such as reduced fines, reduced sentence, or deferred prosecution. The fundamental elements are:

1. Implement written policies, procedures, and standards of conduct.
2. Designate a compliance officer and compliance committee.
3. Conduct effective training and education.
4. Develop effective lines of communication.
5. Conduct internal monitoring and auditing.
6. Enforce standards through well-publicized disciplinary guidelines.
7. Respond promptly to detected offenses and undertaking corrective action.

1. Implement Written Policies, Procedures, and Standards of Conduct

The compliance officer, legal counsel, and board must work in concert to develop, implement, monitor, and enforce an effective compliance program. First, clear policies and procedures should be established regarding regulated actions, such as handling protected health information and combatting fraud, waste, and abuse. The OIG Web site contains a range of guidance on which policies, procedures, and standards of conduct should be included in the compliance program. CMS has also issued guidelines on mandatory Medicare Advantage and Prescription Drug Plans compliance programs that can aid organizations in developing and revising their compliance program to meet requirements.

The policies, procedures, and standards should articulate the organization's commitment to comply with all applicable federal and state regulations and standards, and compliance expectations should be described as embodied in the standards of conduct. Guidance should also be provided to employees and others on how to address and respond to suspected, detected, or reported compliance issues. Members of the organization should also be instructed on how to communicate compliance issues to appropriate internal compliance personnel. The policy should provide a detailed description of how suspected, detected or reported compliance issues will be investigated and resolved by the organization. A policy of non-intimidation and non-retaliation for good faith participation in the compliance program should also be memorialized including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

> The board and senior management have a responsibility to oversee compliance programs and can be held accountable for violations when there is substandard oversight or there is a culture of non-compliance within the organization.

Other elements of the compliance program may include training requirements for combatting fraud, waste, and abuse; the reporting structure for compliance-related issues; information on other reporting mechanisms, such as a telephone hotline; the methods that will be employed for investigation; and addressing compliance issues. The compliance program should also include a description of the means and schedule for regular updates.

Standards or a code of conduct should detail the principles and values of the organization; the expectation that all employees will act in an ethical manner; a description of the reporting mechanism for fraud, waste, and abuse; and how issues will be handled. The standards of conduct should be approved by the organization's full governing body and include a commitment to compliance and lawful conduct by every member of the organization. Compliance documents should be reviewed and updated regularly to reflect changes in laws and regulations. The compliance program should be distributed to new employees within 90 days of initial hiring, whenever there are updates and on an annual basis.

2. Designate a Compliance Officer and Compliance Committee

Organizations should designate a compliance officer who is chiefly responsible for the compliance program and for compliance issues that may arise. In addition, if your organization's size and operations allow for it,

there should be a compliance committee to oversee the program and advise the compliance officer.[48] Members of the compliance committee should include some combination of the following representatives: compliance officer, general counsel, internal audit, risk management, human resources, privacy officer, a board member, CEO, COO, CFO, nursing, a physician, and information technology. The compliance officer and committee will be responsible for overseeing and enforcing the organization's compliance program. In choosing the officer and committee, the organization should consider the independence of the compliance officer and committee as a key component of an effective compliance program that will demonstrate commitment to fostering a culture of compliance within the organization.

OIG guidelines recommend that the compliance officer be a member of senior management with direct access to the governing body and senior management to ensure that compliance reports will directly reach the CEO or president of the organization. The compliance officer should have the authority to provide in-person reports to senior leaders and the board. It is a best practice to require board approval before terminating a compliance officer.

Concerning the compliance committee, OIG guidelines recommend that the committee is positioned to advise the compliance officer and provide oversight of the compliance program. The committee should have decision-making authority over compliance-related issues. The committee should also have responsibility for developing strategies to promote compliance and detection; reviewing and approving compliance training; and providing regular reports to senior executives and the board.

As stated above, if the organization has the resources, the compliance officer should be separate from legal counsel. OIG guidelines pose the question: "Does the compliance officer have independent authority to retain legal counsel?" This question suggests that in-house counsel may not be well suited to serve the advising needs of the organization's compliance officer, and that having the option to seek outside counsel on compliance issues may better preserve the officer's independence. Additionally, CMS guidelines for Medicare Advantage organizations and prescription drug plans state that the compliance officer should not serve in both compliance and operational areas because it creates a conflict of interest. Additionally, a recent Deferred Prosecution Agreement[49] between the DOJ and HSBC Private Bank (Suisse) SA required the separation of the compliance officer from counsel and elevated the compliance officer's position in the organization's hierarchy. Organizations with existing compliance programs in place that do not require the separation of the legal and compliance functions should consider updating their program documents to separate the two roles.

In-house counsel may not be well suited to serve the advising needs of the organization's compliance officer, and having the option to seek outside counsel on compliance issues may better preserve the compliance officer's independence.

3. Conduct Effective Training and Education

The board and senior management have a responsibility to oversee compliance programs and can be held accountable for violations when there is substandard oversight or there is a culture of non-compliance within the organization. In considering the liability of the board, the "Park doctrine" established by a Supreme Court ruling found that "criminal liability [does not] turn on 'awareness of some wrongdoing' or 'conscious fraud.'"[50] In addition, the court observed, "it is equally clear that the government establishes a *prima facie* case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."[51] Thus, a board member or member of senior management does not have to have participated in fraud or have actual knowledge of wrongdoing to be held liable for an organization's wrongful acts. A board member or member of senior management may be held liable for violations for failing to act if he was in a position of responsible compliance authority.

The OIG is focused on holding Responsible Corporate Officials accountable for healthcare fraud and the responsible corporate officer doctrine is applied extensively in criminal healthcare cases. For example, the OIG excluded from the Medicare program a chairman of a large nursing home for his responsibility in alleged substandard care of residents and also excluded the CEO, general counsel,

48 The Governance Institute's biennial survey data shows that most boards combine the audit and compliance functions in a single committee, but there is no single best practice that works for all boards. We recommend that all boards ensure that the compliance function is assigned to a board committee with the proper expertise and level of independence required to effectively fulfill that responsibility.

49 U.S. DOJ, "Justice Department Announces Deferred Prosecution Agreement with HSBC Private Bank (Suisse) SA" (press release), December 10, 2019.

50 *United States v. Park*, No. 74-215 (1975).

51 *Ibid.*

and CMO of Purdue Frederick for 12 years due to their misdemeanor convictions for misbranding OxyContin.

The board must exercise reasonable oversight with respect to the implementation and effectiveness of compliance programs. While the board may delegate oversight of the compliance program to a committee, it remains accountable for reviewing its status. Training and education on the compliance program is required, and the board should have the means to prove active engagement in the oversight of the program.

Senior management must be engaged in oversight of the program and must ensure that the compliance officer has the credibility, authority, and resources needed to monitor and enforce the compliance program. Senior management must receive regular reports on the compliance program and must be aware of all governmental compliance enforcement activity.

All compliance programs should also include a training program and educational resources for personnel at all levels of the organization, including board members. Without proper training, personnel will not be able to understand their obligations, to identify potential compliance issues or to report issues to the appropriate authority in a timely manner.

When organizations operate transparently and promote a culture of compliance, their compliance programs are generally more effective at preventing, detecting, and addressing issues when they arise.

All employees must receive compliance-related training including the CEO, senior executives and management, the governing body, and any independent physicians with staff privileges. This includes related and downstream entities as well. Initial training should be conducted at the time of hiring. When new requirements emerge, the training should be updated and employees should receive the updated version of the compliance program. Training should be conducted company-wide annually thereafter. Documentation of employee training as evidence of compliance should be recorded and retained for each training event.

Additionally, the compliance officer and compliance committee should also receive regular training, and they should make efforts to stay informed of new compliance requirements through various channels, such as conferences, webinars, industry publications, and the OIG Web site.

4. Develop Effective Lines of Communication

When organizations operate transparently and promote a culture of compliance, their compliance programs are generally more effective at preventing, detecting, and addressing issues when they arise. To promote transparency and a culture of compliance, organizations should:

- Create a code of conduct that demonstrates a commitment to compliance.
- Identify conflicts of interest early and address them immediately.
- Ensure regular and effective training.
- Conduct internal audits to ensure compliance with applicable contractual and legal obligations.
- Maintain clear records of compliance issues and their resolution.
- Report potential violations to the appropriate authority without undue delay.

In addition to implementing the steps above to promote transparency and compliance, an organization should develop and maintain effective lines of communication. Communication between personnel and the compliance officer helps with compliance since open lines encourage employees to seek advice and clarification and enables a quick response to compliance-related issues.

Communication between the board/upper management and the compliance officer should take place regularly to ensure that the board and senior leadership are briefed on compliance issues and program effectiveness. Regular contact between the board and compliance officer also promotes a culture of compliance since the issues will be discussed routinely and clearly.

A clear policy should be established for reporting compliance issues and concerns without fear of retaliation. Utilizing multiple methods of communication will aid in ensuring open and effective lines of communication. Methods may include:

- Newsletters
- Email
- Flyers/posters with contact information
- Telephone hotlines
- Regular meetings
- Intranet postings
- Training materials with clear contacts

5. Conduct Internal Monitoring and Auditing

An effective compliance plan will also include a method for conducting regular internal audits of the organization to identify and address potential compliance issues. Regular internal audits may minimize the effects of non-compliance since the audits can detect compliance issues in their early stages. In some cases, an internal audit may even prevent a compliance violation from ever arising by enabling an organization to pinpoint and correct weaknesses that can lead to non-compliance. As part of the internal auditing process, an organization should create an audit plan and update the plan regularly to reflect changes in the organization as well as to applicable statutes and regulations. Compliance processes,

policies and actions should be reviewed proactively, not reactively, and reviewed on a regular basis. In addition, include reviews of all areas covered by the compliance program, such as coding, contracts, and quality of care. The cause of any compliance issues identified during the internal audit should be evaluated, and corrective action plans should be established to address each issue and implement those plans immediately. Results from the audit should be reported to senior management.

An ineffective compliance program can lead to unnecessary violations and enforcement actions, which could have been prevented by ensuring maintenance of a program that encourages and aids in complying with all applicable legal and ethical standards.

6. Enforce Standards through Well-Publicized Disciplinary Guidelines

In order for compliance programs to be effective, employees must have an incentive to adhere to the program. This is where establishing and enforcing clear disciplinary guidelines becomes important. Disciplinary guidelines should strike the right balance between consistency and flexibility. This will ensure that employees understand there will be consequences for non-compliance, but will also enable your organization to adapt disciplinary proceedings according to the situation. As part of this step toward compliance, an organization should establish progressive disciplinary procedures and clear consequences for violations, for example:

1. Verbal warning
2. Written warning
3. Re-training
4. Termination
5. Reporting for criminal sanctions

Disseminate disciplinary guidelines and ensure employees are aware of them. Disciplinary guidelines should be applied uniformly across the organization and at all levels of the organization. The CMS Guidelines offer more specific advice as to the contents of disciplinary guidelines. At a minimum, the disciplinary procedures should articulate expectations for reporting compliance issues and assisting in their resolution; identify non-compliance or unethical behavior; and provide for timely, consistent, and effective enforcement of standards.

7. Respond Promptly to Detected Offenses and Undertake Corrective Action

Responding promptly to detected offenses and taking corrective action demonstrates a commitment by the organization to compliance and, in some cases, can reduce the potential liability and damage resulting from non-compliance. Establish a system to respond to any issues promptly. Conduct a reasonable inquiry into any potential non-compliance, and complete the inquiry as quickly as possible. Use the system to track the issues and their resolution. The board and/or senior management must take appropriate corrective action to correct the current problem and deter future violations. Such corrective actions may include:

Next Steps

Once an organization has implemented a compliance program, the program should be evaluated and measured for effectiveness on a regular basis. An ineffective compliance program can lead to unnecessary violations and enforcement actions, which could have been prevented by ensuring maintenance of a program that encourages and aids in complying with all applicable legal and ethical standards. After implementation, an organization can take the following steps to help maintain an effective compliance program:

- Set benchmarks and measurable goals.
- Measure attainment of goals regularly.
- Investigate failure to meet goals.
- Report results to the board.
- Assess where the problems are and suggest solutions.
- Provide adequate funding.
- Ensure sufficient support throughout the entity, including upper management.

In addition, the board must remain informed about:

- Outcomes
- Notices of non-compliance
- Results of internal and external audits
- Open/closed corrective action plans
- Corrective action appropriately and timely implemented and tested for effectiveness (CMS Mandatory Compliance Programs)

Be Prepared for Government Inquiry

It is critical to the success of a compliance program to establish credibility early to ensure employees know the risks associated with not following the policies, procedures, and standards of conduct. There should be an unequivocal requirement that contact with enforcement agencies be communicated immediately.

Reduce the burden of responding to the document request by verifying retention and destruction policies. Be in a position to quickly provide the items the government will want at the outset.

Show cooperation by presenting the government with details of the organization's operations and information storage by offering tangible evidence of systemic success. This can be accomplished by readily providing the government with specific examples that show the compliance program is not only well established but operational. Be able to provide them with specific instances where the organization has elevated compliance over profits.

When to Consult Outside Counsel

While the board may be well equipped and the hospital has an effective compliance program and plan overseen by strong internal counsel and a compliance officer, there are still instances when it is necessary to involve outside counsel. Such instances include:

- Any contact, subpoena, or inquiry from a governmental entity such as the DOJ or the OIG
- Credible allegations of criminal conduct
- Senior management or board members directly involved in a complaint or investigation
- A nuanced analysis when the hospital or health system needs an outside written opinion
- An overtaxed or understaffed compliance department, which is unable to conduct a thoroughly documented investigation
- A matter when maintaining legal privilege is particularly important and where third parties may need to be hired for investigation or review purposes
- A potential settlement with a governmental agency or relator is being negotiated
- Responding to an audit request from Unified Integrity Contractors (UPICs)
- The legal department or counsel for a third-party vendor contacts the health department or health system about a compliance issue
- External validation of the compliance department's effectiveness is needed
- The hospital or health system is without a compliance officer or is developing an entirely new compliance program

Conclusion

In the wake of a new administration and with billions in relief funds going to healthcare providers across the country as a result of the COVID-19 pandemic, it's a safe bet that healthcare fraud enforcement will be a hot topic for years to come.

Regulatory compliance must be a priority for every healthcare organization. Boards must not only be knowledgeable about healthcare regulatory issues, but they need to establish an organizational culture of compliance and provide oversight and assistance to compliance officers and in-house legal counsel in dealing with operational and hospital management issues.

The monetary penalties associated with false claims and other compliance violations add even more pressure for hospitals, healthcare systems, and other healthcare companies already faced with growing financial challenges. These factors mean that regulatory compliance must be a priority for every healthcare organization. Boards must not only be knowledgeable about healthcare regulatory issues, but they need to establish an organizational culture of compliance and provide oversight and assistance to compliance officers and in-house legal counsel in dealing with operational and hospital management issues. Boards should take advantage of the wide range of available compliance resources. Additionally, outside legal counsel can serve as an effective bridge between the board, executive leadership, the chief compliance officer, and the in-house legal department. Organizations that fail to capitalize on the strengths of both their internal and external resources could find themselves in precarious positions.

Organizations that establish an effective compliance program using the seven fundamental elements described in this white paper will position themselves for success in all areas, from reducing the organization's risk for legal liability to increased transparency, more effective reporting to the board leading to a better-informed board and more effective decision making, and ultimately, creating an organizational culture that supports patient safety and quality of care.

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